

REMARKS

This responds to the Final Action, dated December 27, 2006. Claims 1, 43 to 65 were acted upon by the Examiner.

Claims 1, 49, 52, and 55 to 65 have been amended. Claims 53 and 54 have been canceled without prejudice. Withdrawn claims 2 and 32 have been canceled without prejudice. No claims have been added. Accordingly, claims 1, 43 to 52 and 55 to 65 are presented for examination.

Reconsideration of the present application in view of the above amendments and the following remarks is requested respectfully.

SUMMARY OF THE EXAMINER'S ACTION

Claim Rejections

Claims 49, 52, 54, 60, and 62 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention.

Applicants respectfully traverse the Examiner's rejections and objections.

Claim Objections

Claims 57 to 59 and 61 to 65 are objected to for depending from a rejected base claim.

DISCUSSION

Amendments to the Claims

Support for the amendment to claim 1 is found in page 13, lines 24 to 27; and page 26, line 15, to page 27, line 4, of the application

Claims 57 to 59, 61, and 63 to 65 have been re-written in independent form.

Claims 49, 52, 54, 60, and 62 have been amended to delete the recitation "or use".

Claim 52 has been amended to clarify use of the phrase "the gene".

No new matter has been added.

Discussion of the Art Rejections

(1) Applicants' Claims Are Not Anticipated under Section 102(b) in view of Teng et al.

The present amendments have been provided in order to move prosecution forward as applicants maintain their previous assertions that the previous obviousness rejections are deficient.

Claims 1, 43 to 51, and 53 to 56 stand rejected under 35 U.S.C. §102(b), as anticipated by Teng et al. (WO 99/01579). Teng et al. discloses "penetration enhancers" useful for transport of oligonucleotides across the mucosa of the alimentary canal. Page 47, lines 4 to 9, of Teng et al. discloses a solution containing 1% caproate (C10) which is used to perfuse rat ileum. A 1% C10 solution is about 58 mM (MW of capric acid = 172.3; $1 \text{ mmol}/172.3 \text{ mg} \times 500 \text{ mg}/50 \text{ ml} = 0.058 \text{ mmol}/\text{ml} = 58 \text{ mmol}/\text{L} = 58 \text{ mM}$). Such a high concentration of C10 is useful for lysing cells in a cell layer so that the layer is permeablized, but is much too high for permeablizing individual cells. Thus, Teng et al. teaches that a high C10 concentration is useful to permeablize the mucosal membrane so that nucleic acids can reach the bloodstream.

In contrast, presently amended claim 1 recites "wherein the amount of enhancer effective to enhance the intracellular delivery is about 0.01mM to 30mM when said enhancer has a carbon chain length of from 9 to 14 carbon atoms and 0.01mM to 120mM when said enhancer has a carbon chain length of 8 carbon atoms" Thus, Teng et al. discloses a different concentration than the presently amended claims.

Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. §102 in view of Teng et al. be withdrawn.

(2) Applicants' Claims Are Not Unpatentable under Section 103(a) over Teng et al. in view of Lewin et al. (GB2319773A).

Claims 1 and 52 stand rejected under 35 U.S.C. §103, as being unpatentable over Teng et al. in view of Lewin et al. (GB2319773A). As discussed above, Teng et al. discloses C10 penetration enhancers at a concentration of 58mM. This concentration is outside the scope of the presently amended claims. Accordingly, Teng et al. does not disclose a required element of the presently amended application. The disclosure of Lewin et al. does not overcome the deficiencies of Teng et al.

Accordingly, Applicants respectfully request that the rejection of claims 1 and 52 under 35 U.S.C. §103, as being unpatentable over Teng et al. in view of Lewin et al. be withdrawn.

Discussion of the Section 112, Second Paragraph, Rejections

Claims 49, 52, 54, 60, and 62 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that the recitation “or use” of claims 49, 52, 54, 60, and 62 lacks antecedent basis. Claims 49, 52, 54, 60, and 62 have been amended to delete the recitation “or use”.

Claim 52 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that the recitation “the gene” of claim 52 lacks antecedent basis. Claim 52 has been amended to recite “wherein said nucleic acid-based drug is a gene and said gene is selected from the group consisting of...”.

Applicants submit that the claims as presently amended overcome the Examiner’s Section 112, second paragraph, rejections. Accordingly, Applicants respectfully request that the rejection of claims 49, 52, 54, 60, and 62 under 35 U.S.C. §112, second paragraph, be withdrawn.

Discussion of the Claim Objections

Claims 57 to 59 and 61 to 65 are objected to for depending from a rejected base claim. Claims 57 to 59, 61, and 63 to 65 have been re-written in independent form. Claim 60 now depends from independent claim 58 or 59. Claim 62 now depends from independent claim 61.

Accordingly, Applicants respectfully request that the objection to claims 57 to 59 and 61 to 65 be withdrawn.

In re application of Michael Seveso, et al.
Application No. 09/743,173

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A favorable action on the merits is requested respectfully. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 19-5425.

Respectfully submitted,

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